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Description

The invention relates to medical devices for removing stones from the kidneys, ureter or biliary duct according to the first part of claim 1.

While stones can be removed by direct surgery, it is much preferred that the stone be located by use of an endoscope and removed by endoscopic guidance of a device inserted through a working channel of the endoscope.

Examples of instruments used in the past for removal of stones include:

- forceps with axially-directed grasping arms, and
- basket devices such as shown in
  - **US-A- 1 677 671** (COUNCILL), and
- baskets with helically arranged wires as shown in
  - **US-A- 2 943 626** (DORMIA) according to the first part of claim 1 and
  - **US-A- 4 347 846** (DORMIA),

e.g. similar to those sold by C.R. BARD, Inc. of Murray Hill, New Jersey.

The technical **problem** of the invention regarding this prior art is a device that can dislodge and remove stones more effectively than prior devices.

The **solution** to this problem is accomplished by the characterizing part of claim **1**.

The remaining claims go further in specifying the invention.

Preferred Embodiment

We first briefly describe the drawings:

Drawings

Fig. 1 is a diagrammatic view of one embodiment of a device according to the invention;

Fig. 2 is an enlarged side sectional view of the distal portion of the device of Fig. 1 with the basket extended, while Fig. 3 is a similar view with the basket retracted;

Figs. 4 and 4a are side and plan views of a forming device used to shape the spring arms;

Figs. 5 through 5c are sequential diagrammatic views of the preferred forming process;

Fig. 6 is an enlarged plan view of a strip in position on the forming device of Fig. 4, while Fig. 6a is a similar view of the strip used in the described device, with a second pair of arms in section;

Figs. 7 and 7a are side and plan views, respectively, of the step of joining the strip at the distal tip;

Fig. 8 is a side view of the strips with their proximal ends inserted into a sleeve, while Fig. 8a is an enlarged and section view at the lines 8a-8a of Fig. 3;

Fig. 9 is a diagrammatic view of the device inserted into the kidney via a nephroscope; and

Fig. 10 is a view similar to Fig. 9 of the device inserted into the ureter via a ureterscope.

Structure

Referring to Fig. 1, a preferred medical retriever device 10 according to the invention consists of a distally bulbous basket 12, a narrow, enlongated sheath 14 and a handle 16 at the proximal end. The sheath is a plastic tube, e.g. PVC or teflon®, about 27.5 inches (70 cm) in length and sized for passage through the working channel of an endoscope. The sheath is 5 French (.065 inch (1.65 mm) outer diameter), with an internal diameter of .044 inch (1.12 mm).

In Fig. 2, the distal portion 18 of the device is shown in more detail. Basket 12 comprises four outwardly bowed, generally flat spring arms 20', 20", 21', 21", opposed pairs of arms being formed each of a single length of strip-form 20, 21 material formed into a loop at distal tip 22, with the ends 24, 25 disposed in sleeve 26 at the proximal end of the basket. The strip-form arms, each about 3.0 inches (7.6 cm) in length, are typically of 304 stainless steel. The strips have their narrow dimension (x dimension) disposed radially and their broad dimension (y dimension) disposed circumferentially about the basket. In the embodiment shown, the strips are .005 inch (0.13mm) by .015 inch (0.38 mm) in x and y dimension, respectively. Adjacent distal tip 22, first strip portions 28 lie at small acute angles to the axis A, of the basket in a manner to facilitate collapse of the basket when it is retracted into the sheath, as will be described more fully below. Proximally and outwardly from portions 28, the spring strips have a curve shape consisting of a first outwardly directed (concave) arc 30 followed by a second, more proximal, inwardly directed (convex) arc 32, the centers of the arcs, e, f, respectively, being separated by about 0.035 inch (0.89 mm). The maximum diameter, M, of the basket is reached at a position spaced dimension L_1 from the distal tip. In the preferred embodiment, M equals about 0.67 inch (1.7 cm), the length of the basket, L, is about 1.0 inch (2.6 cm), and L_1 equals about 1/4 L.

Referring to Fig. 5 et seq., the basket spring strips are formed in their novel configuration on the pin fixture 34 shown in Figs. 4 and 4a. Referring to Figs. 4a and 6, with the intersection of the X and Y axes, i.e. point (0, 0), at the center point of lower pin 1, the center points of the other pins in fixture 34 are disposed as follows (all dimensions are in inches): pins 2-2 at (0.030, -0.030) and (-0.030, -0.030); pins 3-3 at (0.060, -0.040) and (-0.060,

-0.040); and pins 4-4 at (1.060, -0.040) and (-1.060, -0.040). (In millimeters, the dimensions are: pins 2-2 at (0.76, -0.76) and (-076, -0.76); pins 3-3 at (1.5, -1.0) and (-1.5, -1.0); and pins 4-4 at (26.9, -1.0) and (26.9, -1.0) and (-26.9, -1.0).) All pins have diameter of about .020 inch (0.51 mm).

A first length of spring strip material 20 is centered between pins 1-1 and the ends of the strip are bent parallel (Fig. 5) to form a small radius curve without kinking. As shown in Fig. 4, outward sets of pins are progressively shorter to allow strip 20 to be moved toward the base 36 after each step to engage further sets of pins for the next steps. Thus during the step just described, the strip is positioned on pins 1-1 at a height between r and s; for the next step, the strip is moved toward the base between s and t, to allow engagement about pins 2-2. Strip ends 24 are bent upward to approximately a 60° angle (Fig. 5a). The strip is again moved toward the base, and the ends 24 are bent about pins 3-3 to an angle of approximately minus 30° (Fig. 5b). The distance between the centers of the arcs formed about pins 2 and 3 control the shape of the curves described above. For the embodiment described, this distance is about 0.035 inch (0.89 mm). As the strips are bent in the direction of their thickness, the curves generally conform closely to the pin circumferences. The strip is again moved toward the base and the ends 24 are bent about pins 4 to an angle of about 90° (Fig. 5c). In Fig. 6, the strip is shown in enlarged scale formed about the pins.

Referring to Figs. 7 and 7a, two strips 20, 21 formed as above are disposed at right angles, with the center protrusions formed on pins 1-1 in alignment. The undersurface 35 of strip 20 is disposed in close, flat-surface-to-flat-surface juxtaposition with the upper surface 35' of the strip 21. The strips are then joined securely, e.g. by silver soldering, to form tip 22, of minimal length, e.g., as compared to the length of the basket.

The undersurfaces 35 of portions 38 of the ends of the strip lying between the curves formed about pins 3 and 4 is rolled over a 0.25 inch (6.35 mm) diameter dowel to work harden the material into a permanent bow.

The arms of the strip are bent downward to bring the opposed ends 24, 25 of the strips 20, 21 into face-to-face contact and the ends are inserted into sleeve 26, 19.5 gauge stainless steel about 0.39 inch (1 cm) in length, and silver soldered. As shown in Fig. 8a, the springness of the strips urges the ends radially outward against the walls of the sleeve 26 to form a uniform square pattern within.

Referring to Fig. 6a, the arms deform about the distal tip 22 with arcs 30, 32 flattening slightly to form an outwardly extending shoulder while the width of the proximal end of the tip narrows slightly.

Due to the special curved formation of the spring arms, the diameter of the basket 12 increases quickly from the distal end 22 of the basket giving the basket its novel, distally bulbous shape, the usefulness of which in dislodging and capturing stones and the like will be described more fully below. In the preferred embodiment, no such curves are formed at the proximal end of the basket, thus the diameter change occurs more gradually in this region.

After the proximal ends of the spring strips 20, 21 are secured, the distal end of shaft 40, .012 inch (0.30 mm) diameter stainless steel, is secured within sleeve 26. Surrounding shaft 40 and extending over the major portion of its length is stainless steel coil 44, about .038 inch (0.96 mm) diameter. Secured to the proximal end of shaft 40 is handle sleeve 42, 19.5 gauge stainless steel 4.75 inch (about 12 cm) long. The ends of the shaft are typically secured by soldering, which is performed in a manner to fix the ends of the coil at least close to the ends of the sleeves. The shaft provides stiffness and torque, the coil provides flexibility and strength. Positionable on handle sleeve 42 is pin vise handle 46 provided to facilitate projection, retraction and rotation of basket 12 by movement of sheath 14 relative to the coil and shaft.

Operation

Referring to Figs. 1 and 3, sheath 14 is advanced distally to retract basket 12 into the sheath. As the sheath advances, the basket narrows and lengthens. When the basket is fully retracted, the pin vise 47 on handle 46 is tightened to secure the basket in retracted position. (In the embodiment shown in Fig. 3, the basket may be drawn fully into the sheath; in other embodiments, the distal tip 22 is of a size to act as a stop against the tip of the sheath to limit retraction.)

The surgeon positions the viewing lens of an endoscope within the body of a patient and by manipulating the scope, he visually locates a stone or the like to be removed. For example, the kidney is like a sponge with a central cavity the size of a walnut surrounded by spongy walls with numerous shallow crevices, or calyces, within which the stones typically lodge. In Fig. 9, the surgeon has positioned a nephroscope 50 with the tip positioned to view a stone 52 lodged in calyces 54 of the kidney 56. The device 10 with the basket retracted is inserted through the working channel of the scope. The surgeon extends the basket 12 from the sheath and the strip-form arms spring outward to restore the basket to the desired bulbous shape. As the surgeon manipulates the basket under visual guidance of the scope by rotating the handle

and moving it in and out to try to dislodge the stone and move it into the volume of the basket, the relatively broad, flat surfaces of the spring strips act to deflect the spongy kidney tissue surrounding the stone while the distally enlarged volume of the basket close to the distal tip allows the surgeon to act with more effect to dislodge and capture the stone. It has been observed that the generally flat, tissue-deflecting surfaces of the spring strips of the device described; the extended dimension of the strip lying in the circumferential direction, which adds stiffness in that direction; the relatively stiff structure formed by the face-to-face disposed strips at the distal end, the adjacent strips acting as braces during engagement for dislodging; as well as the enlarged, bulbous distal shape of the basket, all serve to make this device highly effective for dislodging and removing stones and the like.

Once the stone is manipulated into the basket through the openings between the strips, the basket is partially retracted into the sheath to close the basket about the stone and hold it securely. Depending upon the size of the stone, and the likelihood of finding other stones to be removed, the sheath and the stone are either withdrawn through the endoscope, or the entire scope is removed.

Other Embodiments

Other embodiments are within the following claims. For example, a different number of strip-form arms may be employed, with consideration being given, for the particular application, for the open space required for entry of the stones into the volume of the basket. Where an odd number of arms is desired, the distal end of the odd arm is secured at the top, as shown in dashed line in Fig. 7a. Within certain broad aspects of the invention, the basket may be comprised of a number of single arms, or the curves may be provided at both ends of the basket.

Baskets of other sizes may be formed. For example, for the uses described above, the maximum basket diameter, M, may range between 0.47 and 0.87 inch (1.2 cm and 2.2 cm), the basket length, L, may range between 0.87 and 1.18 inches (2.2 and 3.0 cm), and L_1 may vary between 1/4 L and about 1/3 L.

The device in these and other sizes is also useful with other endoscopes for retrieval of stones or the like from other parts of the body. For example, in Fig. 10 the retriever device 10 is shown in use via the working channel of a ureterscope 60 to remove a stone from the upper ureter. (The scope has been inserted, without an incision, via the bladder 64). Once a stone 62 is observed, the surgeon extends the tip of the sheath, with the basket retracted, beyond the stone and then withdraws the sheath to allow the basket to expand. The generally flat-surface of the expanded arms aids in dilating the passage walls to help dislodge the stone and allow it to enter the basket for removal.

Claims

1. **Medical retriever device (10)**
   - sized and adapted for use through the working channel of an endoscope
   - for removing stones and the like from kidneys, ureter or biliary duct,

   comprising
   - an elongated, narrow **sheath** (14),
   - a **basket** (12)
     - of relatively large diameter
     - extendible from the distal end of said sheath (14),
     - collapsible when withdrawn into said sheath (14),
     - defined by a multipticity of
       - spaced apart, radially outwardly bowed
     - generally flat spring strips (20', 20", 21', 21")
       - extending generally axially of said sheath (14) in the withdrawn condition and
       - joined at respective distal and proximal ends of said basket (12), and
   - a **shaft** (40)
     - inside said sheath (14)
     - and secured to said basket (12)
     - to project, retract and rotate said basket (12) relative to the distal end of said sheath (14),

   characterized in that
   - said **basket** (12) has
     - a generally bulbous form
       - adjacent its distal end,
       - its maximum diameter (M) being spaced from its distal end a distance (L_1) of equal to between about one quarter and one third its overall length (L, Fig. 2); and
     - first portions (28) of said generally flat spring strips (20', 20", 21', 21")
       - closely adjacent the distal extremity of said basket (12)
       - lie at an angle close to the axis (A) of said basket (12) in a manner to facilitate collapse of said basket (12) during withdrawal into said sheath (14),
     - at least two of said generally flat spring strips (20', 20", 21', 21")

- being disposed face to face at the distal end of said basket (12) and
- joined together in a manner contributing stiffness to the bulbous end of said basket (12), and
- second portions of said generally flat spring strips (20', 20", 21', 21")
  - proximal of said first strip portions (28)
  - extending radially outwardly of said first strip portions (28), and
  - having a curved shape comprised sequentially of oppositely directed arcs (30,32),
- said generally flat spring strips (20', 20", 21', 21") having
  - their narrow dimension disposed radially and
  - their broad dimension disposed circumferentially about said basket (12),
- the ratio of radial to circumferential dimensions of said generally flat spring strips (20', 20", 21', 21") being
  - between about 1 : 2 and 1 : 4.

2. Device of claim 1,
characterized in that
- said basket (12) is comprised of
  - at least four of said generally flat spring strips (20', 20", 21', 21")
    - joined at the distal tip (22) of said basket (12).

3. Device of claim 1,
characterized in that
- at least one pair of said generally flat spring strips (20', 20", 21', 21") is comprised of
  - a single length of strip-form material formed into a loop.

4. Device of claim 1,
characterized in that
- said ratio is
  - about 1 : 3.

5. Device of claim 5,
characterized in that
- said generally flat spring strips (20', 20", 21', 21") have
  - a radial dimension of about 0.13 mm and
  - a circumferential dimension of about 0.38 mm.

6. Device of claim 1,
characterized in that
- the proximal ends (24, 25) of said generally flat spring strips (20', 20", 21', 21") are
  - joined within a sleeve (26)
  - retractable into said sheath (14).

Revendications

1. **Extracteur médical (10)**
- dimensionné et apte à l'utilisation à travers le canal de travail d'un endoscope
- destiné à extraire des calculs et similaires à partir des reins, de l'uretère ou des canalicules biliaires.

constitué par
- une **gaine** étroite, allongée (14),
- un **panier** (12)
  - d'un diamètre relativement large
  - extensible à partir de l'extrémité distale de la gaine (14),
  - repliable lorsqu'il est en retrait ou rentré dans la gaine (14),
  - défini par une multiplicité de
    - bandes élastiques généralement plates (20', 20", 21', 21")
  - espacées entre elles, pliées radialement vers l'extérieur
  - s'étendant de façon générale axialement par rapport à la gaine (14) à l'état de retrait et
  - raccordées aux extrémités respectives distale et proximale du panier (12), et
- un **axe** (40)
  - à l'intérieur de la gaine (14)
  - et fixé sur le panier (12)
  - pour faire saillir, rétracter et mettre en rotation le panier (12) par rapport à l'extrémité distale de la gaine (14)

caractérisé en ce que
- le **panier** (12) présente
  - une forme de façon générale bulbeuse
  - contigüe à son extrémité distale,
  - son diamètre extérieur (M) étant espacé de son extrémité distale sur une distance (L_1) égale à entre environ un quart et un tiers de sa longueur totale (L, figure 2) ; et
- des premières portions (28) des bandes élastiques de façon générale plates (20', 20", 21', 21")
  - étroitement contigües à l'extrémité distale du panier (12)
  - se situent à un angle proche de l'axe (A) du panier (12) de manière à faciliter le repliage du panier (12) pendant le retrait à l'intérieur de la gaine (14),
- au moins deux des bandes élastiques

généralement plates (20', 20", 21', 21")
- étant disposées face à face sur l'extrémité distale du panier (12) et
- raccordées ensemble d'une manière conférant de la rigidité à l'extrémité bulbeuse du panier (12) et

- des secondes portions de bandes élastiques généralement plates (20', 20", 21', 21")
  - proximales aux premières portions de bande (28)
  - s'étendant radialement vers l'extérieur des premières portions de bande (28) et
  - ayant une forme courbe constituée séquentiellement par des arcs dirigés de façon opposée (30, 32)
- les bandes élastiques généralement plates (20', 20", 21', 21") ayant
  - leurs dimensions étroites disposées radialement et
  - leurs dimensions larges disposées circonférentiellement autour du panier (12),
- le rapport entre les dimensions radiales et circonférentielles des bandes élastiques généralement plates (20', 20", 21', 21")
  - se situant entre environ 1 : 2 et 1 : 4

2. Dispositif selon la revendication 1, caractérisé en ce que
   - le panier (12) est constitué par
     - au moins quatre des bandes élastiques généralement plates (20', 20", 21', 21")
       - raccordées sur la pointe distale (22) du panier (12).

3. Dispositif selon la revendication 1, caractérisé en ce que
   - au moins une paire des bandes élastiques généralement plates (20', 20", 21', 21") est constituée par
     - une longueur unique de matière formant une bande en boucle.

4. Dispositif selon la revendication 1, caractérisé en ce que
   - le rapport est
     - d'environ 1 : 3.

5. Dispositif selon la revendication 5, caractérisé en ce que
   - les bandes élastiques généralement plates (20', 20", 21', 21") comportent
     - une dimension radiale d'environ 0,13 mm et
     - une dimension circonférentielle d'environ 0,38 mm.

6. Dispositif selon la revendication 1, caractérisé en ce que
   - les extrémités proximales (24, 25) des bandes élastiques généralement plates (20', 20", 21', 21") sont
     - raccordées à l'intérieur d'une enveloppe (26)
     - rétractable à l'intérieur de la gaine (14).

Patentansprüche

1. **Medizinischer Fremdkörper-Entferner** (10)
   - bemessen und ausgebildet zum Einsatz durch den Arbeitskanal eines Endoskops
   - zum Entfernen von Steinen od. dgl. aus Niere, Harnleiter oder Gallengang,

   mit
   - gestrecktem, engem **Schlauch** (14),
   - einem **Korb** (12)
     - von relativ großem Durchmesser,
     - ausfahrbar aus dem distalen Ende des Schlauchs (14),
     - zusammenlegbar bei Einfahren in den Schlauch (14),
     - gebildet durch eine Anzahl
       - getrennter, radial auswärts gebogener
     - im wesentlichen flacher Federstreifen (20', 20", 21', 21"),
       - im wesentlichen axial zum Schlauch (14) nach Einfahren verlaufend und
       - an entsprechenden distalen und proximalen Endes des Korbs (12) verbunden, und
   - einer **Welle** (40)
     - innerhalb des Schlauchs (14) und
     - gesichert am Korb (12)
     - zum Ausfahren, Einfahren und Drehen des Korbs (12) relativ zum distalen Ende des Schlauchs (14),

   gekennzeichnet dadurch, daß
   - der **Korb** (12) besitzt:
     - im wesentlichen Birnenform
       - nahe seinem distalen Ende,
       - wobei sein Höchstdurchmesser (M) von seinem distalen Ende beabstandet ist um einen Abstand (L_1) gleich zwischen einem Viertel und einem Drittel seiner Gesamtlänge (L, Fig. 2); und
     - erste Abschnitte (28) der im wesentlichen flachen Federstreifen (20', 20",

21', 21")
- sehr nahe zum distalen Ende des Korbs (12) und
- unter einem Winkel nahe zur Achse (A) des Korbs (12) liegend zum leichteren Zusammenlegen des Korbs (12) beim Einfahren in den Schlauch (14),

- mindestens zwei der im wesentlichen flachen Federstreifen (20', 20", 21', 21")
  - gegenüberliegend angeordnet am distalen Ende des Korbs (12) und
  - verbunden zum Versteifen des birnenförmigen Endes des Korbs (12), und
- zweite Abschnitte der im wesentlichen flachen Federstreifen (20', 20", 21', 21")
  - proximal zu den ersten Streifenabschnitten (28),
  - im wesentlichen radial auswärts zu den ersten Streifenabschnitten (28) verlaufend und
  - mit gekrümmtem Profil aus aufeinanderfolgend entgegengesetzt gerichteten Bögen (30, 32),
- wobei die im wesentlichen flachen Federstreifen (20', 20", 21', 21")
  - mit ihrer schmalen Ausdehnung radial und
  - mit ihrer breiten Ausdehnung in Umfangsrichtung um den Korb (12) verlaufen,
- wobei das Verhältnis von radialer zu Umfangs-Ausdehnung der im wesentlichen flachen Federstreifen (20', 20", 21', 21")
  - zwischen ca. 1:2 and 1:4 beträgt.

2. Fremdkörper-Entferner nach Anspruch 1, *gekennzeichnet dadurch, daß*
   - der Korb (12) besitzt
     - mindestens vier der im wesentlichen flachen Federstreifen (20', 20", 21', 21"),
     - die an der distalen Spitze (22) des Korbs (12) verbunden sind.

3. Fremdkörper-Entferner nach Anspruch 1, *gekennzeichnet dadurch, daß*
   - mindestens ein Paar der im wesentlichen flachen Federstreifen (20', 20", 21', 21") aus
     - einem einzigen Längsstück von zu einer Schleife verformtem Bandmaterial besteht.

4. Fremdkörper-Entferner nach Anspruch 1, *gekennzeichnet dadurch, daß*
   - das Verhältnis
     - ca. 1:3 beträgt.

5. Fremdkörper-Entferner nach Anspruch 5, *gekennzeichnet dadurch, daß*
   - die im wesentlichen flachen Federstreifen (20', 20", 21', 21") besitzen:
     - eine radiale Ausdehnung von ca. 0,13 mm und
     - eine Umfangs-Ausdehnung von ca. 0,38 mm.

6. Fremdkörper-Entferner nach Anspruch 1, *gekennzeichnet dadurch, daß*
   - die proximalen Enden (24, 25) der im wesentlichen flachen Federstreifen (20', 20", 21', 21")
     - mit einer Manschette (26) verbunden sind,
     - die in den Schlauch (14) einfahrbar ist.

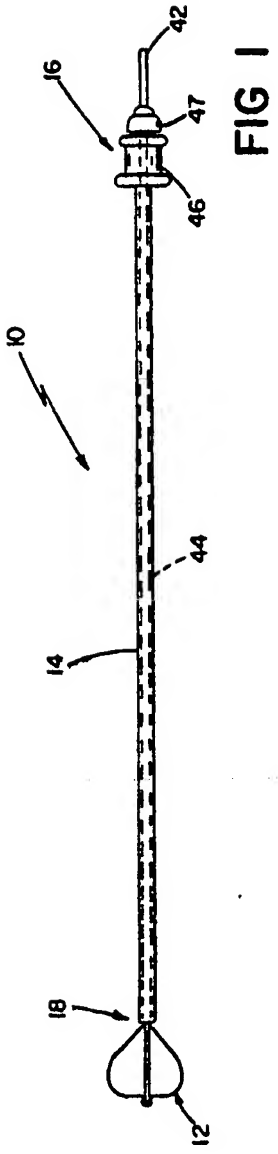


FIG 1

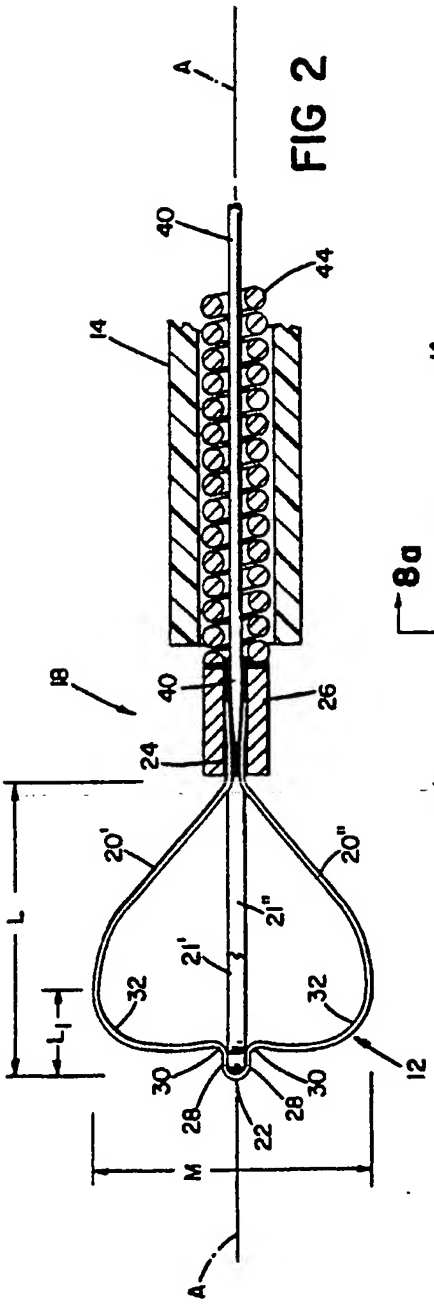


FIG 2

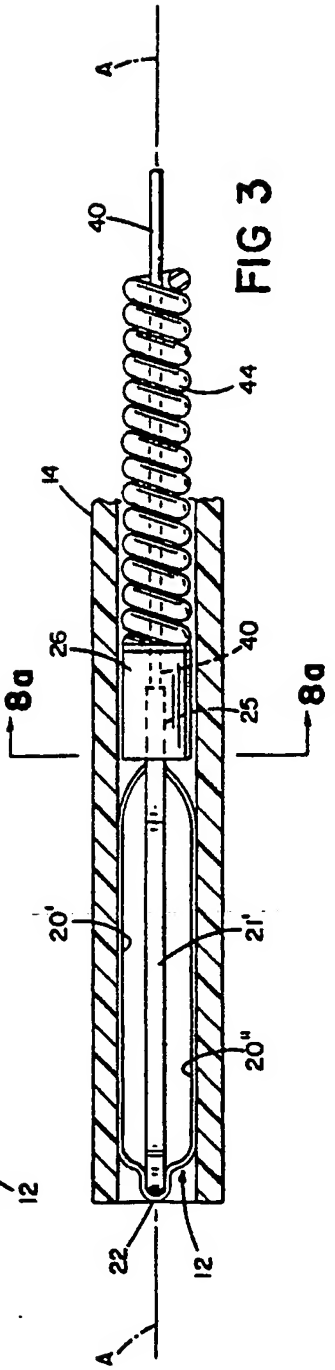
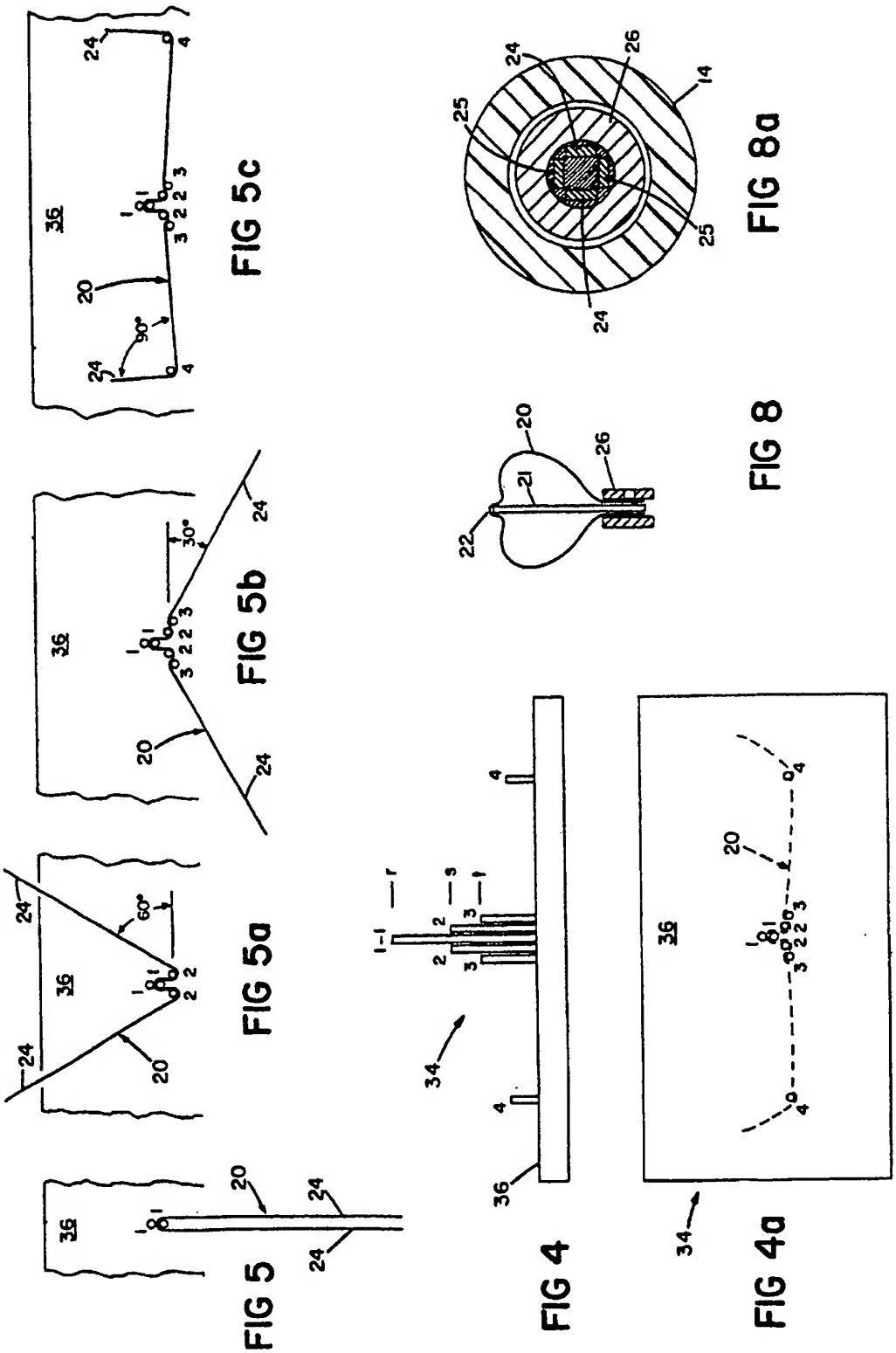


FIG 3


36
20
24
90°
60°
30°
34
FIG 5
FIG 5a
FIG 5b
FIG 5c
FIG 4
FIG 4a
FIG 8
FIG 8a
22
21
26
25
14

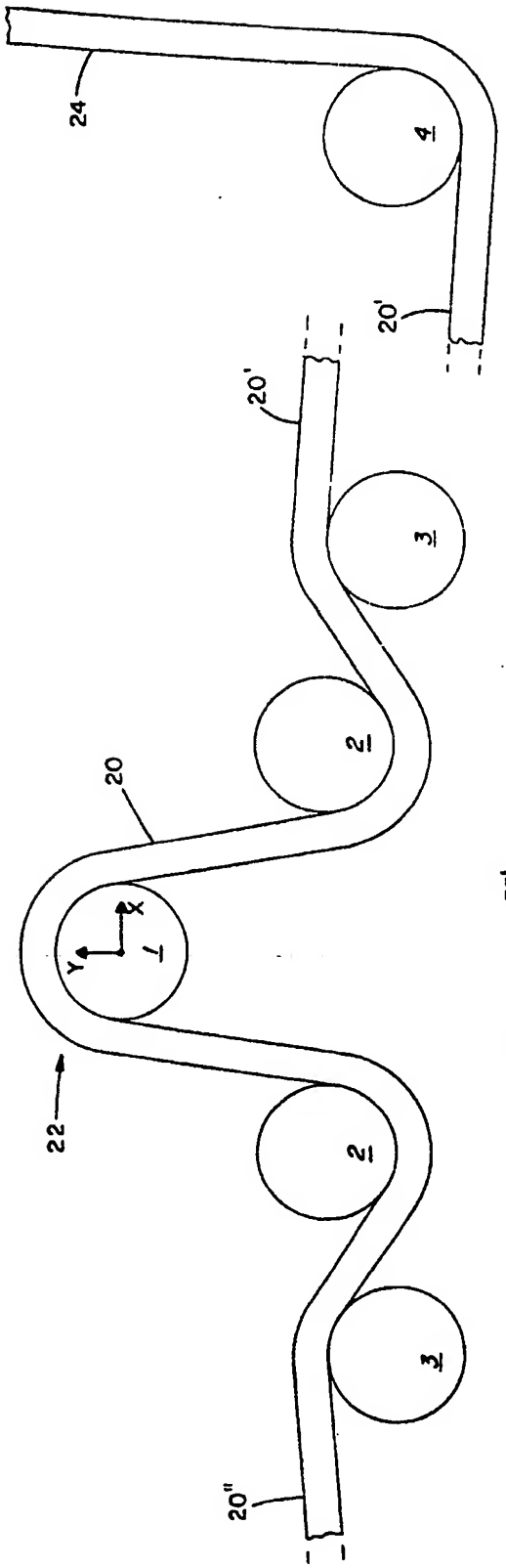


FIG 6

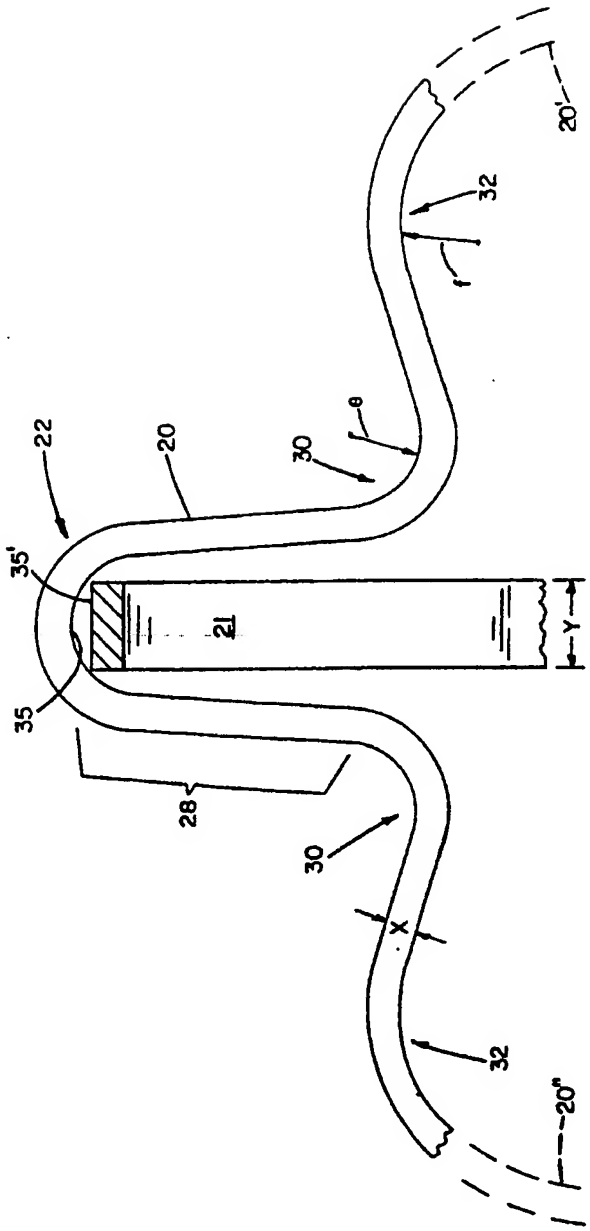


FIG 6a

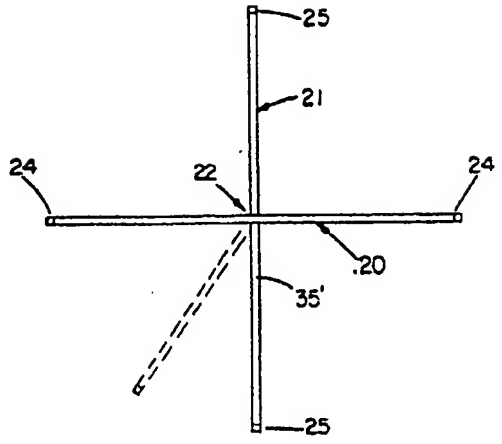


FIG 7a

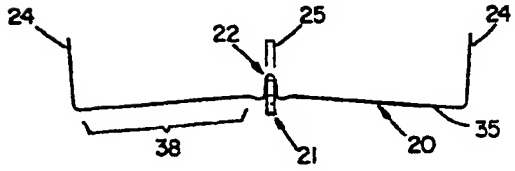


FIG 7

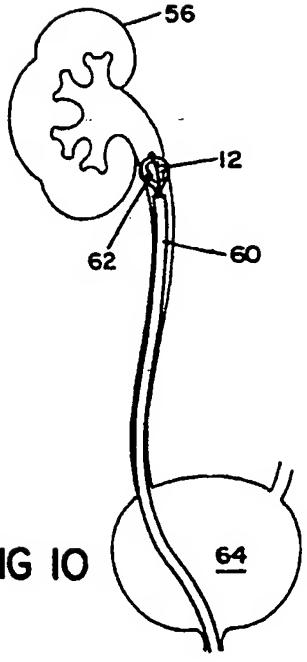


FIG 10

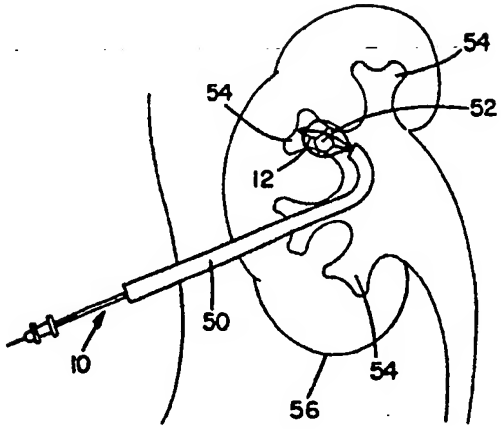


FIG 9